

Introduction:

The purpose of this document is to give the end users of the Growth Direct® System definitions regarding cassette errors that may be observed. A full list of errors can be found in our TSC0034 document.

Failure to Orient or Misaligned: The pre-imaging alignment required to ensure that the sample is in the same orientation at each timepoint did not complete successfully or the alignment was poor quality determined by analysis of image movement.

Vision Analysis Errors: A generic error indicating that one or more of the preprocessing analysis steps failed. Examples include - dust on the vision lid obstructing key features of the cassette (most common), poor camera focus, not enough fiducial (circle features on film), incomplete region of interest (membrane), high background fluorescence.

Image Shift: The image has shifted from the last time point. This can occur due to the image deck dial plate being non-concentric or defects within the cassette/consumable base. This will present as a *Vision Analysis Error*.

Count Prior to Endpoint: A class of vision analysis error that occurs when the organism growth is very high and cannot be counted accurately similar to confluent growth when counting visually. This includes Overgrowth (high fluorescence from large organisms) and Too Numerous Too Count (high density of organisms).

False Positive: An artifact (dust/fiber/other fluorescence) is counted incorrectly as a CFU by the system. Please incubate the cassette/sample further for visual confirmation with the human eye. Samples can be left in the GDS or incubated in a traditional incubator.

Canceled Cassettes: Cassettes could be canceled by the system for many reasons. For example, all events listed below:

Past Due - Cassette missed its scheduled timepoint by more than 2 hours.

Failed Height Check - The vision lid is not on the cassette base properly.

Unreadable Barcode - The serial number barcode was not readable by the system.

Unknown Sample Barcode - The cassette was not ordered on the system before it was loaded.

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